

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOT FOR PUBLICATION

**Abbott Laboratories and Fournier
Laboratories Ireland, Ltd.,**

Plaintiffs,

v.

**Lupin Limited and Lupin Pharmaceuticals,
Inc.,**

Defendants.

Civil Action No. 10-1578 (DMC / JAD)

**Abbott Laboratories and Fournier
Laboratories Ireland, Ltd.,**

Plaintiffs,

v.

**Mylan Pharmaceuticals Inc. and Mylan
Inc.,**

Defendants.

Civil Action No. 10-2073 (DMC / JAD)

**Abbott Laboratories and Fournier
Laboratories Ireland, Ltd.,**

Plaintiffs,

v.

**Watson Laboratories, Inc.-Florida, Watson
Pharma, Inc. and Watson Pharmaceuticals,
Inc.,**

Defendants.

Civil Action No. 10-2139 (DMC / JAD)

**Abbott Laboratories and Fournier
Laboratories Ireland, Ltd.,**

Plaintiffs,

v.

Actavis Elizabeth LLC, and Actavis Inc.,

Defendants.

Civil Action No. 10-2352 (DMC / JAD)

OPINION

JOSEPH A. DICKSON, U.S.M.J.

This will address Defendants' application to strike the Corrected Expert Report of G. Patrick Stahly, Ph.D. (the "Corrected Report") which was served by Plaintiffs on May 11, 2012. Defendants seek to strike the Corrected Report as untimely because it was served one month prior to trial, seven months after the close of expert discovery, and in violation of the Third Amended Scheduling Order (ECF 56). For the reasons set forth below, Defendants' application is denied, subject to their right to depose Dr. Stahly.

I. Background

This case concerns a pharmaceutical patent infringement suit. Plaintiffs jointly own the rights to U.S. Patent No. 7,259,186 (the "186 Patent"), which currently expires on January 7, 2025, and claims novel salts of and formulations of fenofibric acid. *Id.* at ¶ 15, ECF No. 1. These salts and formulations of fenofibric acid are useful as lipid and cholesterol lowering agents for treatment of adults with increased triglyceride levels. *Id.* at ¶ 17. Plaintiffs market choline fenofibrate delayed release capsules under the name TRILIPIX. *Id.* at ¶ 18. Defendants submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture, use, and sell choline fenofibrate delayed release capsules as generic versions of TRILIPIX. *Id.* at ¶ 21. Plaintiffs thereafter filed the present suit for patent infringement. *Id.* at. ¶¶ 25-31.

On July 15, 2011, Plaintiffs served Defendants with Dr. Stahly's Expert Report (the "Original Report"). On May 11, 2012, Plaintiffs served Defendants with the Corrected Report.

In the Corrected Report, Dr. Stahly states that he intends to correct paragraphs 62 and 63 of his initial report. Corrected Report, ECF 96-2, ¶ 4. Specifically, with regard to paragraph 62, Dr. Stahly wishes to change the first sentence¹ from:

The Krause patent cited by Dr. Gould contemplates that the acids from which are selected one component of the claimed mixtures, illustrated by the acids gemfibrozil, clofibrate, bezafibrate, and fenofibrate, "react to form pharmaceutically acceptable metal and amine salts."

Original Report, ECF 94-4, ¶ 62, to the following:

The Krause patent cited by Dr. Gould does not disclose fenofibric acid or any salts thereof. The Krause patent only contemplates acids of gemfibrozil, and bezafibrate and "pharmaceutically acceptable metal and amine salts" of gemfibrozil and bezafibrate.

Corrected Report, ECF 96-2, ¶ 4. With regard to paragraph 63, Dr. Stahly wishes to change the first four sentences² from:

The information provided by the Krause patent is only that pharmaceutically acceptable salts could potentially be made. That essentially constitutes no information at all. A person having ordinary skill in the art would not understand from the Krause patent why preparation of any specific salt of fenofibric acid would be of value, how to prepare any specific salt of fenofibric acid, or what would be the properties of any specific salt of fenofibric acid that could be prepared. Simply listing other counter-ions as possibly forming salts with fenofibric acid does not constitute anticipation that those will be solid, crystalline, stable, or otherwise usable as APIs.

Original Report, ECF 94-4, ¶ 63, to the following:

The information provided by the Krause patent is only that pharmaceutically acceptable salts of gemfibrozil and bezafibrate could potentially be made. That constitutes no information at all with respect to fenofibric acid or salts thereof. A person having ordinary skill in the art would not understand the Krause patent to be disclosing fenofibric acid or salts thereof and would not understand from the Krause patent why preparation of any specific salt of fenofibric acid would be of value, how to prepare any specific salt of fenofibric acid, or what would be the properties of any specific salt of fenofibric acid that could be prepared. Therefore, Krause does not anticipate the '186 patent alone or combined with Berge. Even under Dr. Gould's misreading of the Krause reference, simply listing other counter-ions as possibly

¹ The remainder of paragraph 62 is unchanged.

² The remainder of paragraph 63 is unchanged.

forming salts with fenofibric acid would not constitute anticipation that those will be solid, crystalline, stable, or otherwise usable as APIs.

Corrected Report, ECF 96-2, ¶ 4.

II. Discussion

Defendants contend that the Corrected Report must be stricken because: (1) it is unduly prejudicial under Third Circuit precedent; and (2) it is inconsistent with a binding judicial admission made by Plaintiffs. Defendants further argue that the Corrected Report did not reflect a mere correction, but rather “reversed key admissions made by Dr. Stahly in the Original Report and recanted his sworn deposition testimony.”³ Def. Ltr., ECF 94, p. 2.

Plaintiffs make several arguments in response. First, Plaintiffs assert that Dr. Stahly’s Corrected Report corrects a mistake made in two (2) out of eighty-eight (88) paragraphs in his Original Report and does not change the ultimate opinion in that Report. Moreover, Plaintiffs argue the Corrected Report does not require any response from Defendants since their expert, Dr. Gould, issued a Report prior to Dr. Stahly’s Report which contained information that contradicts Dr. Stahly’s Original Report regarding whether or not the Krause patent specifically discloses fenofibric acid and salts. Furthermore, Plaintiffs argue that Dr. Gould relies on twenty-five other prior art references in his validity analysis and that therefore there is no prejudice to Defendants to allow the Corrected Report.

Plaintiffs also argue that the Corrected Report is properly served under Federal Rule of Civil Procedure 26(e) which requires litigants to supplement or correct disclosures made during discovery in a timely manner. Plaintiffs point out that on May 11, 2012, Dr. Stahly issued, and

³ Since Dr. Stahly’s deposition testimony was based on his Original Report, and, as discussed more fully below, the Court finds that any issues can be cured either through a supplemental deposition or during cross examination during the bench trial, either of which would logically supplant his former deposition testimony, this Opinion will focus on the revisions to the Original Report.

Plaintiffs served, the Corrected Report. Accordingly, Plaintiffs argue, the Corrected Report is timely under Rule 26(e).

Finally, Plaintiffs argue that their reliance on Dr. Stahly's Original Report in their Summary Judgment motion papers is not a binding admission. Ultimately, Plaintiffs' position is that Dr. Stahly made a mistake in his Original Report, continued to stand by his Original Report during his deposition, and subsequently, after additional review, realized he was initially incorrect regarding his own analysis and immediately corrected the mistake. Under these circumstances, Plaintiffs argue, the Corrected Report should be admitted.

Both parties agree that the proper legal analysis to be applied is found in *Meyers v. Pennypack Woods Home Owners*, 559 F.2d. 894 (3d. Cir 1997). The Court of Appeals for the Third Circuit stated in *Meyers*,

Underlying the cases to which we have adverted are these basic considerations:

- (1) the prejudice or surprise in fact of the party against whom the excluded witnesses could have testified,
- (2) the ability of the party to cure the prejudice,
- (3) the extent to which the waiver of the Rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case and/or other cases in the Court,
- (4) bad faith or willfulness in failing to comply with the Court's Order.

559 F. 2d. 894 at 904-905.

After applying the *Meyers* factors, this Court finds that the Corrected Report should be allowed. First, in applying the first two factors regarding prejudice and the ability to cure, it must be kept in mind that the Corrected Report neither expanded Dr. Stahly's ultimate opinion nor asserted new theories in support of Plaintiffs' position. He merely corrects (or revises as the case may be) his understanding of one piece of prior art. More importantly, he does not change his ultimate opinion on what that prior art represents in the context of this case. Defendants'

reliance on Judge Cavanaugh's Opinion in *Pfizer, Inc. v. Ivax Pharmaceuticals, Inc.*, 2009 WL 29054 (D.N.J. 2009) is misplaced. Therein, Judge Cavanaugh precluded testimony that would have expanded the scope of the expert's prior testimony. In this case, there is no expansion of the opinion, testimony or Report of Dr. Stahly.

The Court has closely examined the Defendants' arguments regarding how they are prejudiced. First, Defendants argue that their expert, Dr. Gould, "relied on Dr. Stahly's original interpretation of Krause in forming his invalidity opinions concerning Claims One and Two of the '186 Patent." Def. Ltr., p.8, ECF 94. Dr. Gould's Report, however, was issued prior to Dr. Stahly's Report, which was issued in rebuttal to Dr. Gould. Even so, Defendants argue that Dr. Gould "had no reason to specifically address *why* one of ordinary skill in the art would interpret Krause in this manner." *Id.* The Court finds that there is no reason why this cannot be accomplished at the trial. If Defendants deem it necessary to explain why Dr. Stahly is now wrong or what the Krause patent discloses,⁴ Dr. Gould should be perfectly capable of doing that on the stand with Dr. Stahly's Corrected Report having been reviewed over the last several weeks prior to the trial. Finally, this Court does not accept Defendants' argument that they "may have significantly altered their litigation strategy had they known of Dr. Stahly's new, 'corrected' interpretation of Krause ten months ago." *Id.* at 9. This Court has read Dr. Gould's Rebuttal Report and specifically focused on Paragraph 39 where Dr. Gould recognizes that Dr. Stahly opines that "the Krause reference cited in [Gould's] Expert Report does not 'anticipate' the asserted claims because the patent does not 'disclose the salts of fenofibric acid listed in the asserted claims, their properties, or how they may be synthesized.'" (Rebuttal Report ¶ 39, ECF 96-4) Dr. Gould goes on to state that "Krause specifically discloses salts of fenofibric acid," *Id.*

⁴ Keeping in mind that the experts and the parties already, and have always, disagreed on whether the Krause patent renders the '186 Patent obvious.

and goes on to disagree with the rest of Dr. Stahly's conclusions, never mentioning that Dr. Stahly's Original Report agreed that Krause discloses salts of fenofibric acid. The Court can find no reliance by Dr. Gould on Dr. Stahly's Original Report. Furthermore, Dr. Gould ends Paragraph 39 by stating, "Should Dr. Stahly provide an explanation for his assertion, I reserve my right to respond." *Id.*

Accordingly, this Court concludes that Dr. Stahly's Corrected Report, which corrected one underlying conclusion regarding the Krause patent and did not change his ultimate opinion that the Krause patent does not anticipate the '186 Patent, is not an expansion of his Original Report and opinion nor is it a new theory leading to the prejudice set forth in prior case law.

Furthermore, this Court finds that any prejudice which exists can easily be overcome in this bench trial by either the cross examination of Dr. Stahly regarding his somewhat last minute catch of a mistake regarding the Krause patent and what exactly it does disclose, or, if the Defendants wish, a deposition of Dr. Stahly as set forth below.⁵

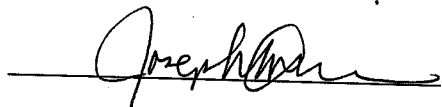
Finally, this Court finds no bad faith on the part of Plaintiffs. While Defendants argue that Plaintiffs' violation of this Court's Scheduling Order, which says that any failure to comply with that Order will "result in sanctions pursuant to Fed. R. Civ. P. 16(f) and 37," ECF 30, constitutes bad faith under *Meyers* as a result of the delay in realizing Dr. Stahly's mistake and failure to explain how the mistake occurred, this Court finds that there is no bad faith on the part of the Plaintiffs. The position in which the Plaintiffs find themselves does not appear to this Court to be a calculated position seeking to place the Defendants at a disadvantage, thereby implicating bad faith.

⁵ To the extent Defendants seek to depose Dr. Stahly prior to the trial, which will not be adjourned, Plaintiffs shall produce Dr. Stahly at this Courthouse on a date mutually agreed to by the parties, for one two-hour deposition. Plaintiffs shall bear Dr. Stahly's fee for the deposition.

This Court also finds that the statements contained in the Plaintiffs' Summary Judgment briefs do not constitute binding admissions. First, Plaintiffs correctly state that Local Rule 56.1(a) limits the effects of undisputed facts to Summary Judgment motions. In this case, Defendants' motion for Summary Judgment has been denied. The Court need not decide the largely unexplored question of when a statement in a Statement of Material Facts Not In Dispute that is not disputed but is qualified by the party opposing the statement becomes binding on such party for other purposes when the Summary Judgment motion has been denied. Judge Cavanaugh's Opinion does not specifically address the statements or response regarding Paragraph 50 in his Opinion denying the motion. Indeed, the Opinion states that the issue of whether Patent '186 is obvious, and therefore invalid, "present[s] exceptionally complicated issues of fact." Opinion, p. 6, ECF 74. The so-called admissions at issue now do not constitute unequivocal, unambiguous concessions that bind the Plaintiffs here. *See, Philadelphia Reinsurance Group v. Employers Ins. Of Wausau*, 61 Fed. App'x 816, 819 (3d Cir. 2003) ("To be binding, judicial admissions must be unequivocal. An unequivocal statement is one that is *clear, unambiguous, and expresses only one meaning.*") (emphasis added); *Brown v. Dunbar Armored, Inc.*, No. 08-3286, 2009 WL 4895237 at *8 (D.N.J. Dec. 10, 2009) (explaining that "[u]nequivocal concessions of fact" made in briefs are judicial admissions that bind the party who makes them") (emphasis added).

III. Conclusion

For the foregoing reasons, Defendants' motion to strike is **denied**.


JOSEPH A. DICKSON, U.S.M.J.

cc: Hon. Dennis M. Cavanaugh, U.S.D.J.